

***Remarks***

Reconsideration of this Application is respectfully requested.

Claim 8 is sought to be cancelled without prejudice to or disclaimer of the subject matter therein, and claims 1, 5-13, 16, 17, 21-28 and 31 are sought to be amended. Upon entry of the foregoing amendment, claims 1-7 and 9-31 are pending in the application, with claims 1 and 17 being the independent claims.

Support for the amendments to claims 1, 5-13, 16, 17, 21-28 and 31 can be found throughout the specification and in the claims as originally filed. In particular, the claims have been amended in order to more accurately define the invention and to make that which was implicit in the claims explicit. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Rejections under 35 U.S.C. § 112, First Paragraph***

The Examiner rejected claims 1-31 under 35 U.S.C. § 112, first paragraph, for allegedly failing to enable one skilled in the art to make and use the invention commensurate in scope with the claims. (See Paper No. 9, page 2.) In particular, the Examiner asserted that

the specification, while being enabling for the process of claim 17 when requiring the conditions of claims 21, 23, 24, 26 and 29, and drying in (a) is to a moisture content of about 0.1% to about 20% as described by the specification (page 7, line 30), does not reasonably provide enablement for other processes differing substantially from the preferred embodiments described in the specification.

(Paper No. 9, pages 2-3.) Applicants respectfully traverse this rejection as it applies to the claimed invention.

Applicants describe in the specification the inventive process for the recovery of an organic acid from a fermentation broth. In particular, the specification discloses, step by step, the components necessary to carry out each of the steps of the process as well as preferred reaction conditions. In addition, Applicants disclose five working examples which enable the claimed invention by demonstrating different conditions by which two exemplary organic acids can be obtained by the inventive process.

The Examiner argued that the specification does not provide enablement for other processes differing substantially from the preferred embodiments. However, "because only an enabling disclosure is required, applicant need not describe all actual embodiments." M.P.E.P. § 2164.02 at 2100-176. As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *See In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. § 112. *See Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987). As such, Applicants

assert that the specification adequately describes how to make and use the claimed invention.

The Examiner also argued that

[u]ndue experimentation would be required to determine conditions substantially different from those of the operative examples that would provide results equivalent to those of the operative examples.

(Paper No. 9, page 2.)

In order for a claim to be enabled, the specification must teach one of ordinary skill in the art to make and use the invention without undue experimentation. The factors that can be considered in determining whether an amount of experimentation is undue have been set forth in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Among these factors are: the amount of effort involved, the guidance provided by the specification, the presence of working examples, the amount of pertinent literature and the level of skill in the art. The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine. *See id.* In addition, the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *See In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985).

*In re Wands* involved an appeal from the Board of Appeals and Patent Interferences, affirming the examiner, rejecting immunoassay claims on the grounds that making anti-HBsAg antibodies for use in the claimed immunoassay, other than the deposited antibody,

would be "unpredictable and unreliable, so that it would require undue experimentation for one skilled in the art to make the antibodies." *Id.* at 735, 8 USPQ2d at 1402. Antibodies other than the one deposited were described only in terms of function and only a general method of making and using them was disclosed in the application. *See id.* The facts showed that IgM antibodies were disfavored because they tended to self-aggregate and precipitate, isolating the correct antibodies required screening hundreds of clones, and the appellant's first four attempts were unsuccessful. *See id.* at 734, 8 USPQ2d at 1402. Nevertheless, the Federal Circuit found that the disclosure satisfied the requirements under § 112, first paragraph. The court based its decision on the fact that the invention could be practiced with "readily available starting materials using methods that are well known in the monoclonal antibody art" and because "practitioners of the art are prepared to screen negative hybridomas in order to find one that makes the desired antibody." *See id.* at 736, 8 USPQ2d at 1406.

Experimentation is not undue merely because it would require testing various conditions encompassed by the claimed invention. As set forth in *In re Wands*, "[t]he test is not merely quantitative since a considerable amount of experimentation is permissible, if it is merely routine." 858 F.2d at 737, 8 U.S.P.Q.2d at 1404. The Examiner is reminded again that in *In re Wands*, the Applicant had to screen hundreds of clones to find one that met the limitations of the claims. *See id.* at 736, 8 U.S.P.Q.2d at 1406.

Further, it is the Examiner's position that

due to the unpredictability of chemical reactions, it would be unpredictable as to substantially different conditions that would provide results disclosed in the specification.

(Paper No. 9, pages 2-3.)

While the predictability of the art can be considered in determining whether an amount of experimentation is undue, mere unpredictability of the result of the experiment is not a consideration. Indeed, in *In re Angstadt*, the Court of Custom and Patent Appeals has specifically cautioned that the unpredictability of the result of an experiment is not a basis to conclude that the amount of experimentation is undue:

[If to fulfill the requirements of 112, first paragraph, an applicant's] disclosure must provide guidance which will enable one skilled in the art to determine, with reasonable certainty before performing the reaction whether the claimed product will be obtained. . . . then all "experimentation" is "undue" since the term "experimentation" implies that the success of the particular activity is uncertain. Such a proposition is contrary to the basic policy of the Patent Act.

537 F.2d at 503, 190 USPQ at 219 (emphasis in the original). As Judge Rich explained in *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991), the statutory enablement requirement is satisfied if the specification "adequately guides the worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility." Applicants assert that they have done so.

The specification clearly shows how to dry a fermentation organic acid-containing broth to obtain an organic acid-containing dried product, how to add the organic acid-containing dried product to a lower alcohol to obtain an alcoholic suspension, how to add a non-organic acid to the alcoholic suspension, and how to remove the insolubles to obtain an organic acid. (See Specification at page 6, line 4, to page 9, line 30.) Accordingly, Applicants specifically point out that the determination of conditions different from those in the operative examples that would provide similar results would be routine because the individual methods, parameters and components were well-known and routine in the art at

the time the invention was made. The Examiner has provided no objective evidence showing that obtaining a desired organic acid according to the inventive process by utilizing and optimizing various conditions was not routine to one of skill in the art at the time the invention was made.

Applicants submit that because of: (1) the availability of routine techniques for preparing and drying fermentation broths; (2) the availability of the desired starting materials and reaction products; (3) the high level of skill in the field of organic chemistry and microbiology; and (4) the direction and guidance provided by the specification, one skilled in the art could routinely make and use the claimed process. Accordingly, withdrawal of this rejection is respectfully requested.

***Rejections under 35 U.S.C. § 112, Second Paragraph***

The Examiner rejected claims 1-31 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (See Paper No. 9, page 3.) In particular, the Examiner asserted that

[t]he term "product (a)" in (b) of claims 1 and 17, "suspension (b)" in (c) of claim 17 and "organic acid (d)" in line 2 of claim 31 are confusing since (a), (b) and (d) each represent a process step rather than a product, suspension or organic acid. It is suggested that -- from step -- be inserted after "product", "suspension" and "acid", and in line 2 of claims 1 and 17, after "comprising" insert -- the following steps --.

(Paper No. 9, page 3.)

Applicants respectfully assert that claims 1, 17 and 31 were definite as originally filed. However, in an effort to facilitate prosecution and in accordance with the Examiner's suggestion, Applicants have amended claims the claims to recite "the steps of" after comprising in claims 1 and 17 and "of step" after "product", "suspension" and "acid" in claims 1, 17 and 31.<sup>1</sup>

The Examiner also indicated that "[c]laim 2 and other claims that recite 'step' are confusing by not having clear antecedent basis for 'step' in claims 1 and 17. The above insertion suggested after 'comprising' in claims 1 and 17 will provide clear antecedent basis." (Paper No. 9, pages 3-4.) Applicants have amended claims 1 and 17 in accordance with the Examiner's suggestion, thereby proving clear antecedent basis for the word "step."

The Examiner further indicated the terms "at step" and "at steps" in claims 5-13, 21, 22 and 24-28 were confusing and suggested replacing the word "at" with the word "in." (*See* Paper No. 9, page 4.) Applicants believe that these claims are not confusing as filed. Nevertheless, Applicants have amended these claims in accordance with the Examiner's instructions.

In addition, the Examiner asserted that claims 5 and 21 "are confusing by not having antecedent basis for 'said organic acid added to said lower alcohol' since claims 1 and 17 do not require adding organic acid to the lower alcohol." (Paper No. 9, page 4.)

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<sup>1</sup>Applicants note that "use of the word 'step,' by itself, does not invoke a presumption that § 112, P 6 applies. For example, method claim elements may begin with the phrase 'steps of' without invoking application of § 112, P 6. The phrase 'steps of' colloquially signals the introduction of specific acts, rather than functions, and should therefore not presumptively invoke application of § 112, P 6." *Seal-Flex, Inc. v. Athletic Track & Court Construction*, 172 F.3d 836, 849 (Fed. Cir. 1999) (Rader, concurring) (citation omitted).

Applicants have amended claims 1 and 17 to recite that the organic acid-containing dried product of step (a) is added to a lower alcohol, thereby removing any alleged confusion.

It was also the Examiner's position that claims 7 and 23 "are confusing by not having clear antecedent basis for 'the reaction temperature.' Claims 1 and 17 do not require a reaction temperature." (Paper No. 9, page 4.) Applicants have amended claims 7 and 23 such that the reaction temperature at which the dehydration and acid reactions occur, which are inherently present in the independent claims, are further limited. Applicants believe that such an amendment removes any possible confusion.

The Examiner asserted that claim 8 is confusing as well "by not having antecedent basis for 'addition of said acid.'" (Paper No. 9, page 4.) Applicants submit that claim 8 was definite as originally filed. However, claim 8 has been canceled, thereby rendering the rejection moot.

According to the Examiner, claim 9 "is unclear by limiting an amount of acid added in step (b) of claim 1 since step (b) of claim 1 does not require adding acid." (Paper No. 9, page 4.) Claim 1 has been amended such that step (b) comprises adding an organic acid-containing dried product. Accordingly, Applicants submit that claim 9 is sufficiently clear.

With respect to claims 6, 13, 16, 22 and 28, the Examiner suggested amendments to remove any alleged statutory problems with the claims. Solely in an effort to expedite prosecution, Applicants have amended the claims in accordance with the Examiner's suggestions.

All of the Examiner's rejections under 35 U.S.C. § 112, second paragraph, have been adequately addressed either by Applicants' amendments and/or remarks. Consequently, Applicants respectfully request that this rejection be withdrawn.



***Rejections under 35 U.S.C. § 103***

The Examiner rejected claims 1-31 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Dumpelmann *et al.*, U.S. Patent No. 5,852,211, in view of Bott *et al.*, EP 0 174 624. (See Paper No. 9, page 5.) Specifically, the Examiner claimed that

[i]t would have been obvious to omit crystallizing NaKGA in the process of Dumpelmann *et al* and instead filter the fermentation solution, dry the resulting filtrate and react the dried filtrate with the lower alcohol in the presence of acid as suggested by Bott *et al* using steps of filtering and drying a fermentation solution without crystallizing in the production of a lactic ester form [sic] a fermentation mixture containing a calcium salt of the lactic acid. Filtering and drying without crystallizing would have been expected to simplify the process of Dumpelmann *et al*, and such simplification would have been motivation to use filtering and drying in place of crystallizing and separating the crystals.

(Paper No. 9, page 6.) Applicants respectfully traverse this rejection.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness. In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation to combine the reference teachings, there must be a reasonable expectation of success, and the references must teach all of the claim limitations. *See, e.g.*, M.P.E.P. § 2143 at 2100-122. Obviousness cannot be established by modifying the teachings of the prior art to produce the claimed invention unless there is some teaching, suggestion or motivation to do so found either in the reference itself or in the knowledge generally available to one of ordinary skill in the art. *See In re Fine*, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). In addition, the mere fact that a reference could conceivably be modified to make the claimed invention does not render the resultant modification obvious

unless the prior art also suggests the desirability of that specific modification. *See In re Mills*, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990).

As disclosed in the specification, "[i]t has been surprisingly and advantageously found that organic acids of a high purity can be recovered at high yields using the whole dried fermentation broth as a starting material." (Specification at page 5, lines 21-23.) Moreover, "[i]t was surprising and particularly advantageous that the fermentation broth could be dried, *e.g.*, spray dried, to obtain an easily handled free flowing powder." (Specification at page 8, lines 3-5.)

Dumpelmann *et al.* teach a process for the conversion of the sodium salt of 2KLG acid, which is present in an aqueous fermentation solution, into an alcoholic solution of the free acid which involves crystallizing the sodium salt and separating the resulting crystals from the fermentation solution. *See* the '211 patent, col. 1, lines 6-12. Bott *et al.* teach a process for obtaining optically pure alkyl lactate from calcium lactate which involves filtering the fermentation mixture while hot. In contrast to these references, the present inventive process does not require that the insolubles be removed by filtration at a high temperature. *See* Example 1, pages 10-11. The omission of a step or an element and the retention of its function is in indicia of nonobviousness. *See In re Edge*, 359 F.2d 896 (CCPA 1966).

In addition, Applicants respectfully disagree with the Examiner's contention that "[f]iltering and drying without crystallizing would have been *expected* to simplify the process of Dumpelmann *et al.*" The cited references disclose, at most, that one skilled in the art might find it "obvious to try" the claimed process. However, whether a particular process

might be "obvious to try" is not a legitimate test of patentability. *See In re Geiger*, 815 F.2d 686, 688 (Fed. Cir. 1987).

In view of the above, Applicants submit that the Examiner has not established a *prima facie* case of obviousness. Consequently, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 103(a) be withdrawn.

### ***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully  
requested.

Respectfully submitted,

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### **Version with Markings to Show Changes Made**

#### ***In the Claims:***

Claim 8 has been canceled.

The following claims 1, 5-13, 16, 17, 21-28 and 31 were substituted for the pending claims 1, 5-13, 16, 17, 21-28 and 31:

1. (Once amended) A process for the recovery of an organic acid from a fermentation broth comprising the steps of:

(a) drying said organic acid-containing fermentation broth to obtain an organic acid-containing [a] dried product;

(b) adding said organic acid-containing dried product of step (a) to a lower alcohol in the presence of a non-organic [an] acid; and

(c) removing insolubles to obtain an organic acid.

5. (Once amended) The process of claim 1, wherein in [at] step (b) the concentration of said organic acid added to said lower alcohol is from about 50 g/L to about 100 g/L.

6. (Once amended) The process of claim 1, wherein in [at] step (a) [the process for] drying comprises spray drying said fermentation broth.

7. (Once amended) The process of claim 1, wherein [the reaction temperature] in [at] step (b) the reaction temperature is from about 25° C to about 60° C.

8. (Once amended) The process of claim 1, wherein in [at] step (b) said dried product is added to a lower alcohol prior to the addition of said acid.

9. (Once amended) The process of claim 1, wherein in [at] step (b) about 1.2 equivalents of said non-organic acid is present [added].

10. (Once amended) The process of claim 1, wherein in [at] step (b) said lower alcohol is selected from the group consisting of methanol, ethanol, propanol, butanol and glycol.

11. (Once amended) The process of claim 1, wherein in [at] step (b) said acid is selected from the group consisting of sulphuric acid, nitric acid, hydrobromic acid, hydrochloric acid and phosphoric acid.

12. (Once amended) The process of claim 11, wherein in [at] step (b) said acid is sulphuric acid.

13. (Once amended) The process of claim 1, wherein in [at] step (c) [the process for] removing insolubles comprises filtration.

16. (Once amended) The process of claim 1, further comprising esterifying said organic acid of step (c) to the corresponding ester.

17. (Once amended) A process for the recovery of an organic acid from a fermentation broth comprising the steps of:

(a) drying said fermentation organic acid-containing broth to obtain an organic acid-containing [a] dried product;

(b) adding said organic acid-containing dried product of step (a) to a lower alcohol to obtain an alcoholic suspension;

(c) adding a non-organic [an] acid to said alcoholic suspension of step (b); and

(d) removing the insolubles to obtain an organic acid.

21. (Once amended) The process of claim 17, wherein in [at] step (b) the concentration of said organic acid added to said lower alcohol is from about 50 g/L to about 100 g/L.

22. (Once amended) The process of claim 17, wherein in [at] step (a) [the process for] drying comprises spray drying said fermentation broth.

23. (Once amended) The process of claim 17, wherein [the reaction temperature] in [at] steps (b) and (c) the reaction temperature is from about 25° C to about 60° C.

24. (Once amended) The process of claim 17, wherein in [at] step (b) said lower alcohol is selected from the group consisting of methanol, ethanol, propanol, butanol and glycol.

25. (Once amended) The process of claim 17, wherein in [at] step (c) about 1.2 equivalents of acid is added.

26. (Once amended) The process of claim 17, wherein in [at] step (c) said acid is selected from the group consisting of sulphuric acid, nitric acid, hydrobromic acid, hydrochloric acid and phosphoric acid.

27. (Once amended) The process of claim 26, wherein in [at] step (c) said acid is sulphuric acid.

28. (Once amended) The process of claim 17, wherein in [at] step (d) [the process for] removing insolubles comprises filtration.

31. (Once amended) The process of claim 17, further comprising esterifying said organic acid of step (d) to the corresponding ester.

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